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IN THE
Supreme Court of the United States
OCTOBER TERM, 1985

FRANK YOUNG, COMMISSIONER OF FOOD AND DRUGS,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF OF NATIONAL PEANUT COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

JAMES M. GOLDBERG *
CHRISTOPHER R. COSTA
ABRAMS, WESTERMEIER
& GOLDBERG, P.C.
1828 L Street, N.W., Suite 660
Washington, D.C. 20036
(202) 785-2050
Attorneys for National Peanut Council, Inc. as Amicus Curiae

* Counsel of Record

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QUESTION PRESENTED

Whether the Food and Drug Administration is required to regulate unavoidable "added" poisonous or deleterious substances in food by adopting tolerances through formal rulemaking, rather than by adopting informal action levels which are applied on a case-by-case basis.

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BRIEF OF NATIONAL PEANUT COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

The National Peanut Council, Inc. ("NPC"), by its attorneys, files this brief as *amicus curiae* in support of the Petitioner, Frank Young, Commissioner of Food and Drugs ("FDA"), and respectfully urges this Court to issue a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit to review the judgment entered in the above-captioned case. This brief is submitted with the written consent of all parties on file with the Clerk of this Court.

INTEREST OF *AMICUS CURIAE*

The National Peanut Council, Inc. ("NPC") is a non-profit Georgia corporation, chartered in 1940, which represents and serves individuals, companies, corporations, and associations engaged in, or providing goods or services to, the production, processing, marketing, or manufacturing of peanuts and peanut products. NPC members include peanut growers and affiliated associations, shellers, custom processors, brokers, manufacturers, and international and allied entities.

The subject matter of the instant case—whether the Food and Drug Administration ("FDA") is required to regulate unavoidable "added" poisonous or deleterious substances in food by means of tolerances promulgated through formal rulemaking, rather than by informal action levels resulting in case-by-case adjudication—is of great concern to NPC, since the specific substances at issue here, "aflatoxins," are chemical byproducts of molds that grow on corn and numerous other agricultural commodities. Furthermore, NPC and its members would be adversely affected by an interpretation of the Federal Food, Drug and Cosmetic Act ("FDCA"), as amended, 21 U.S.C. §§ 301 *et seq.*, that renders adulterated all foods which contain detectable amounts of any unavoidable poisonous or deleterious substance, unless and until a tolerance for each substance and food has been established and promulgated by the FDA.

The interest of NPC is predicated upon the substantial and far-reaching consequences of the result of the instant case. The concern of the *amicus curiae* is that the Court, in formulating the principles to govern the particular dispute involved in the present case, should have the benefit of NPC's views, which may not otherwise be presented in the arguments of the parties, in order to be aware of the broader ramifications of its decision herein.

STATEMENT OF THE CASE

This case presents a challenge to the FDA's method of regulating the interstate commerce of foods which evidence any "added" poisonous or deleterious substance that is required in the production of food or that cannot be avoided by good manufacturing practices. Since the enactment of the FDCA in 1938, FDA has regulated the amounts of substances like aflatoxin principally by issuing "action levels," which announce the level of the particular substance that FDA regards as resulting in adulteration under 21 U.S.C. § 342(a)(1).

Respondents brought this suit to challenge FDA's method of regulation of aflatoxins in corn products. Respondents contended that: (1) FDA should be compelled to adopt a formal aflatoxin tolerance pursuant to 21 U.S.C. § 346, as opposed to an informally implemented action level; (2) the action level, in the alternative, should be made subject to notice-and-comment rulemaking; and (3) certain exemptions to the action level were contrary to law. The United States District Court for the District of Columbia granted summary judgment in favor of FDA on all three issues. Recognizing that an agency's interpretation of its statute is entitled to substantial deference, the court found that FDA's construction of 21 U.S.C. § 346 was reasonable and that 21 U.S.C. § 346 "confers discretionary, not mandatory, authority on the agency to establish tolerances." Pet. App. 31a-32a (footnote omitted). It also concluded that action levels were general statements of policy not requiring notice-and-comment rulemaking and that the exemptions granted were within the agency's discretion. *Id.* at 32a-34a.

The United States Court of Appeals for the District of Columbia Circuit reversed, holding that "the FDA may not proceed by means of action levels rather than toler-

ances," Pet. App. 2a, which require time-consuming and burdensome formal rulemaking procedures and induce inflexible standards. The court reiterated its holding by stating that, "since the existence of a regulation [under 21 U.S.C. § 346] operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." Pet. App. 7a.

NPC, as *amicus curiae*, fully supports Petitioner's statement of the general principles applicable to the instant case and the interpretation of the underlying statutory and regulatory scheme.

SUMMARY OF ARGUMENT

In support of Petitioner's position, NPC respectfully suggests that the Writ of Certiorari be granted as the question raised by Petitioner is substantial and of vital national importance for the following reasons:

(1) The District of Columbia Circuit's interpretation of the FDCA renders almost all foods adulterated and immediately vulnerable to enforcement action, and

(2) The District of Columbia Circuit's interpretation of the FDCA subjects all food producers, processors, and distributors to potential civil and criminal liability for the interstate commerce of agricultural commodities.

ARGUMENT

I. THE COURT OF APPEALS' INTERPRETATION OF THE FDCA RENDERS ALMOST ALL FOODS ADULTERATED AND IMMEDIATELY VULNERABLE TO ENFORCEMENT ACTION.

The court of appeals' interpretation of the FDCA, that "the FDA may not proceed by means of action levels rather than tolerances," [1] was buttressed by an argument which renders almost all foods adulterated under the provisions of the FDCA. The court stated that: "Since the existence of a regulation operates to render the food legally unadulterated, the statute, in our view, plainly requires the establishment by regulation of tolerances before aflatoxin-tainted corn may lawfully be shipped in interstate commerce." Pet. App. 7a. The court interpreted 21 U.S.C. § 346 to mean that any food which contains an "added" unavoidable poisonous or deleterious substance is adulterated unless "a regulation establishing a tolerance is in effect." Pet. App. 7a. The court provided no support for its reasoning, found "little guidance in the legislative history," Pet. App. 9a, and failed to cite any supporting judicial authority for this sweeping and novel interpretation of the FDCA which threatens the nation's food supply.

A necessary implication of the court of appeals' decision is that, before a tolerance is adopted, the presence of *any* "added" poisonous or deleterious substance, even if necessary or unavoidable, renders food adulterated and, therefore, barred from shipment in interstate commerce. Because tolerances can only be adopted through the extraordinarily cumbersome and time consuming procedures

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[1] Pet. App. 2a. The court reiterated its holding by stating that "we have concluded that the FDA is required to issue regulations establishing tolerances in order for food containing unavoidable added poisonous or deleterious substances to be considered unadulterated for the purposes of 21 U.S.C. § 342(a)(1). . . ." Pet. App. 15a.

set forth in 21 U.S.C. § 371(e), many years could well pass during which a substantial portion of the nation's food supply was technically "adulterated." It is clear that the court of appeals failed to fully comprehend the nature of aflatoxin, the practical realities of FDA's regulatory scheme, and the economics of the nation's food supply. Its decision, if not reversed, could completely eliminate the interstate commerce of many agricultural commodities, and apply severe economic forces to intrastate commerce in foods, which will cause prices of certain commodities and their nutrition-substitutes to skyrocket.

In order to clearly appreciate the national interests at stake and the magnitude of the consequences of this decision, NPC, as *amicus curiae*, proffers a brief discussion of the nature of aflatoxins and FDA's regulatory scheme.

1. *The Nature of Aflatoxins.*

The specific "added" poisonous or deleterious substances at issue here, "aflatoxins," are naturally occurring chemical substances produced by the molds *Aspergillus flavus* and *Aspergillus parasiticus*. Aflatoxins occur worldwide in many agricultural commodities; their production is favored by warm temperatures and high moisture levels typical of tropical and subtropical areas, including southern United States. In addition, *A. flavus* invasion of crops and resulting aflatoxin production has also been associated with drought-induced stress, over-maturity, and physical and biological damage.[2] Aflatoxins are frequently found in corn, cottonseed, tree nuts, figs, peanuts, grains, animal products (such as milk and milk products), and meat products of animals which have ingested aflatoxin-contaminated feeds.[3] Although considerable

[2] Diener, U.L., *Deterioration of Peanut Quality Caused By Fungi*, in PEANUTS—CULTURE AND USES, at 523, American Peanut Res. Educ. Assn. 1973; Shotwell, O.L., *Aflatoxin In Corn*, J. Am. Oil Chem. Soc. 54: 216A, 1977.

[3] Stoloff, L., *Aflatoxins—An Overview*, in MYCOTOXINS IN HUMAN AND ANIMAL HEALTH (1977); Stoloff, L., *Occurrence of Mycotoxins*

progress has been made in controlling the aflatoxin contamination of foods and feeds, detoxifying contaminated products,[4] and identifying their significant relationships with the presence of zinc and absence of phytic acid,[5] the complete prevention of mold growth and aflatoxin production in foods appears unattainable at the present time.[6] Since its discovery in the early 1960's, aflatoxin contamination has continued to concern FDA. Soon after the discovery of aflatoxins in foods FDA began a program for their control,[7] and in 1965 FDA established an informal action level of 30 parts per billion ("ppb") total aflatoxins for edible agricultural commodities. In 1969, FDA reduced the action level to its current level of 20 ppb total aflatoxins for human foods and animal feed.[8]

Action levels have permitted FDA the necessary flexibility to set realistic limits on the presence of aflatoxins and other contaminants in foods, free sufficient staff for

in Foods and Feeds, in MYCOTOXINS AND OTHER FUNGAL RELATED FOOD PROBLEMS 149 (J.V. Rodricks ed. 1976); Rodricks, J.V., *Hazards From Nature—Aflatoxins, reprinted from*, FDA CONSUMER, H.E.W. Pub. No. (FDA) 78-2102, May 1979.

[4] *Aflatoxin and Other Mycotoxins: An Agricultural Perspective*, Council for Agricultural Science and Technology, Report No. 80, December, 1979, at 1.

[5] *Soybeans Aflatoxin Control Secret*, News, Chestertown, Maryland, May 2, 1979, *Aflatoxins Continue To Be A Problem*, Countryside, August 1979, at 51.

[6] Stoloff, L., *Aflatoxins—An Overview*, in MYCOTOXINS IN HUMAN AND ANIMAL HEALTH (1977). Major causes of peanut invasion by *A. flavus* and *A. parasiticus* are plant stress, insect damage, mechanical damage, delayed drying, and inadequate ventilation.

[7] Food and Drug Administration, *Compliance Program Guidance Manual, Programs on "Mycotoxins in Foods,"* 1973. This document, or one similar to it, is released each year to provide guidance to FDA District Offices. Summaries of all aflatoxin control activities are contained in these programs.

[8] Pet. App. 22a.

important enforcement duties,[9] and, where necessary, grant exemptions[10] from regulatory action pursuant to those regulations.[11]

2. *FDA's Regulatory Scheme.*

The procedures employed in issuing action levels, under 21 U.S.C. § 342(a)(1), differ from those required for tolerances, under 21 U.S.C. § 342(a)(2)(A). Pet. 4-5, Pet. App. 22a. The most significant difference in the method of issuance is that tolerances are subject to notice-and-comment rulemaking procedures before issuance, under 21 U.S.C. §§ 346, 371(e), while comment opportunities concerning action levels are provided after issuance by FDA. FDA's method of issuing action levels affords the public substantial participation, even though action levels are not subject to the notice-and-comment rulemaking procedures of 21 U.S.C. § 371(e). To establish an action level, FDA publishes a notice in the *Federal Register* announcing the new level and the availability of all relevant data and invites public comment. 42 Fed. Reg. 52814 (Sept. 30, 1977). FDA would require several years, and incur a substantial administrative burden, to establish formal tolerances under 21 U.S.C. § 371(e).

Action levels are public statements of the exercise of FDA's substantial enforcement discretion under 21 U.S.C. § 336 of the FDCA and in furtherance of the agency's responsibilities under 21 U.S.C. § 342(a)(1). The level fixed advises the public of the point at which FDA will

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[9] *United States v. Boston Farm Center, Inc.*, 590 F.2d 149 (5th Cir. 1979) (action to enjoin shipment of corn containing an amount of aflatoxin exceeding FDA's action level), *see also, United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978), *aff'd*, 622 F.2d 157 (5th Cir. 1980).

[10] Pet. App. 24a.

[11] Pet. App. 25a-26a. The FDA has granted two exemptions in eight years. The FDA's 1980 limited exemption was the underlying cause of Respondents' suit.

undertake regulatory action. It is akin to the local police department which, for reasons of resources and priorities, will not stop speeding cars unless they are traveling at speeds in excess of 55 miles per hour, even though the posted limit may be something less.

3. *Consequences of a Tolerance Requirement.*

In light of the pervasive presence of many unavoidable environmental contaminants in the air, soil, and water, most agricultural commodities will be in violation of the FDCA under the court of appeals' interpretation. Furthermore, for over ten years, FDA has publicly advanced this fact: "The Commissioner advises that it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities," 42 Fed. Reg. 52814 (Sept. 30, 1977),[12] and has identified the consequences of a nondetectable-residue requirement which are strikingly similar to the consequences of a tolerance requirement:

> If a nondetectable-residue requirement were automatically applied to environmental contaminants already present in the food supply, enforcement activities could significantly disrupt the food supply. Removing food containing any detectable residue from the marketplace could lead to enforcement action against food commodities not deemed to present any significant risk to public health.

42 Fed. Reg. 17490 (April 1, 1977).

The consequences of the court of appeals' interpretation are: (1) severe FDA administrative burden caused by the promulgation requirements of formal tolerances, (2) findings that, in the absence of tolerances, many foods are adulterated and therefore barred from inter-

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[12] With respect to wildlife, FDA has asserted: "[M]ercury contamination of the aquatic habitat and thereby of fish and shellfish is ubiquitous and unavoidable . . . ." 39 Fed. Reg. 42739 (Dec. 6, 1974).

state commerce, (3) uncertainty and possible civil and criminal liability caused by the expected delay in issuing tolerances and (4) the resulting economic forces on the price of food caused by limiting the nation's food supply.

This case construes FDA's regulatory methods for *all* unavoidable "added" poisonous or deleterious substances, of which aflatoxin presence in corn is only a specific instance. Hence, the consequences of the court of appeals' interpretation must be multiplied by the enormous number of agricultural and animal commodities which may contain contaminants classified as necessary or unavoidable "added" poisonous or deleterious substances and which contaminate our air, water or soil. Therefore, if allowed to stand, the court of appeals' interpretation of the FDCA renders almost all food adulterated and immediately subject to enforcement action under the FDCA. Furthermore, due to the great number of tolerances which must be promulgated, FDA may not be able to remedy this situation for an extended period of time.

II. THE COURT OF APPEALS' INTERPRETATION OF THE FDCA SUBJECTS ALL FOOD PRODUCERS, PROCESSORS, AND DISTRIBUTORS TO POTENTIAL CIVIL AND CRIMINAL LIABILITY FOR THE INTERSTATE COMMERCE OF AGRICULTURAL COMMODITIES.

The court of appeals' interpretation of the FDCA, that absent tolerances any amount of a necessary or unavoidable environmental contaminant renders food adulterated, would severely aggravate the problems noted by Judge Frank's dissent in *United States v. 449 Cases, Containing Tomato Paste*, 212 F.2d 567 (2d Cir. 1954), until such time as FDA promulgates tolerances for all foods. The specific problems noted by Judge Frank, and compounded by the opinion below, include the possibility of dangerous administrative arbitrariness of enforcement of the FDCA without recognizable standards which

activate enforcement and lack of publication of those standards. *Id.* at 577-79. Clearly, the possible imposition of civil liability without notice of tolerances, due to the protracted promulgation requirements of formal tolerances, should be avoided as a disservice to the public and the food industry.

In addition to the imposition of civil liability without notice of enforcement tolerances, the FDCA provides, at 21 U.S.C. § 331, that the interstate commerce of any food that is adulterated is prohibited by the FDCA,[13] and provides for strict criminal liability.[14] Corporate officials, officers, and managers have been held criminally liable for placing adulterated foods into interstate commerce,[15] and this Court has held that they have a "a duty to implement measures that will insure that violations will not occur." *United States v. Park*, 421 U.S. 628 (1975).

Under the interpretation espoused by the court of appeals, the only way that corporate officials could insure that "violations will not occur" would be to halt shipment of most foods, thereby seriously disrupting the nation's food supply and causing product shortages and economic instability. Clearly, the ramifications of the court of appeals decision have not been properly considered and weighed.

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[13] *See United States v. Barnett*, 587 F.2d 252 (5th Cir.), *cert. den.*, 441 U.S. 923 (1979); *United States v. Cassaro, Inc.*, 443 F.2d 153 (1st Cir. 1971).

[14] *Triangle Candy Co. v. United States*, 144 F.2d 195 (9th Cir. 1944) (persons introducing adulterated food in interstate commerce are criminally liable, regardless of their intent or lack of knowledge as to adulteration); *United States v. Dotterweich*, 320 U.S. 277 (1943).

[15] *United States v. Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (S.D. Iowa 1976); *United States v. Colosse Cheese & Butter Co.*, 133 F. Supp. 953 (S.D.N.Y. 1955).

The currently enforced action levels have given the public notice of levels which FDA has determined would give rise to a violation of 21 U.S.C. § 342(a)(1) and thus ameliorates the problems identified by Judge Frank. However, the court of appeals' decision will create an opportunity for arbitrary enforcement, at least until such time as formal tolerances under 21 U.S.C. § 346 can be adopted for the broad range of environmental contaminants.

NPC is seriously concerned that the far-reaching consequences of this case be appreciated. If allowed to stand, the court of appeals' decision threatens either "a cessation of the production and shipment of all foods containing any amount of any 'added' poisonous or deleterious substance, or all segments of the food industry must act in apparent violation of the FDCA until the lengthy process of issuing formal tolerances is completed." Pet. 18.

CONCLUSION

For the reasons set forth herein, the National Peanut Council, Inc., as *amicus curiae* in support of Petitioner's position, respectfully urges this Court to issue a Writ of Certiorari to review the judgment and opinion of the District of Columbia Circuit.

Respectfully submitted,

JAMES M. GOLDBERG *
CHRISTOPHER R. COSTA
ABRAMS, WESTERMEIER
& GOLDBERG, P.C.
1828 L Street, N.W., Suite 660
Washington, D.C. 20036
(202) 785-2050
Attorneys for National Peanut Council, Inc. as Amicus Curiae

* Counsel of Record

Dated: November 19, 1985